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10/809,856	03/26/2004	Osama Kandil	KAN-002-B	7581

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EXAMINER	
LEITH, PATRICIA A	

ART UNIT	PAPER NUMBER
1655	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/809,856	KANDIL, OSAMA	
	Examiner	Art Unit	
	Patricia Leith	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *6-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 20-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-24 are pending in the application.

Claims 6-19 were withdrawn from examination on the merits as they are drawn to an invention nonelected with traverse the response filed on 05/05/06.

Claims 1-5 and 20-24 were examined on their merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a previous Office Action.

Applicant's amendment to the claims has overcome the previous rejection made under 35 USC 102(b) as well as under 35 USC 112 First paragraph Written Description. However, the following new rejection is in order:

Claim Rejections - 35 USC § 112

Claims 1-5 and 20-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application

was filed, had possession of the claimed invention. Claim 1 has been amended to recite 'wherein said lipid fraction comprises about 73 to about 92% by weight polyunsaturated fatty acids'. This information is not found in the Instant specification as filed and is thus considered New Matter.

The Specification teaches that the *N. sativa* 'lipid fraction' obtained "..from evaporating and cooling the solvent-extracted total lipid fraction as described in Example 1 and Figures 1 and 2" contains a fatty acid fraction, a volatile oil fraction and a sterol fraction (see p. 3, Specification). The specification states that "The polyunsaturated fatty acid fraction is present in an amount of *about 73 to about 92% by weight...in the total fatty acid fraction*" (page 4, Instant specification, emphasis added). Therefore, it is clear that it is the fatty acid fraction *of the* lipid fraction which contains 73-92% by weight of polyunsaturated fatty acids, and ***not*** the lipid fraction obtained from the *N. sativa* oil. Thus, recitation of 'wherein said lipid fraction comprises about 73 to about 92% by weight polyunsaturated fatty acids' undeniably increases the originally disclosed amount of polyunsaturated fatty acids *in the lipid fraction* obtained from the *N. sativa* seed oil.

Because all of claims 2-5 and 20-24 are dependant either directly or indirectly upon claim 1, claims 2-5 and 20-24 also contain new matter and hence, are properly rejected under this statute.

Claim Rejections - 35 USC § 103

Claims 1-5 and 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kandil (US 2002/0132019 A1) in view of Ramadan and Mörsel (Nahrung/Food) (2002) in view of Kasting et al. (US 5,041,439 A).

The teachings of Kandil and Ramadan and Mörsel were discussed keenly in previous Office Actions.

Neither reference taught wherein the lipid fraction contained 73 to 92% by weight of polyunsaturated fatty acids as now stated by claim 1. It is further noted that this new limitation is New Matter as discussed *supra*.

Kasting et al. (US 5,041,439 A) taught that polyunsaturated fatty acids were known to be used as transdermal delivery agents (see, for example, col. 3, lines 34-42).

It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. It would have been obvious to one of ordinary skill in the art at the

time Applicants' invention was made to determine all operable and optimal concentrations of polyunsaturated fatty acid components in the lipid fraction disclosed by Kandil (2002) because these fatty acid components were art-recognized result-effective variables as disclosed by Kasting et al. which would have been routinely determined and optimized in the pharmaceutical art.

Response to Arguments

Applicant's arguments have been fully considered, however, were not persuasive in order to overcome the outstanding rejection.

Again, Applicant's amendments to the claims have overcome the previous rejection made under 35 USC 102(b) over Ramadan and Mörsel (Nahrung/Food) and therefore, Applicant's arguments pertaining to the fact that this reference does not explicitly disclose the composition of the claims is accepted due to the amendments to the claims.

Applicant's amendments to the claims have overcome the *previous* rejection under 35 USC 112 First paragraph Written Description (however, a new rejection under this statute has been added due to the amendments most recently made to claim 1). However, Applicant also argues that the previous rejection was unwarranted in that the

Specification teaches that the polyunsaturated fatty acid fraction comprises about 51 to about 61% of octadecadienoic, linoleic acid and 20-25% of octadecenoic acid (and so-forth), thereby indicating that the polyunsaturated fraction contains 'primarily' C18 fatty acids (p. 6, Remarks). However, Applicant is asked to review the previous claim prior to amendment. The claim states that the lipid fraction contained 'primarily' C18 fatty acids, wherein the Specification clearly states that a fraction *of the* lipid fraction, namely, the polyunsaturated fatty acid fraction contained 'primarily' C18 fatty acids. It is clear from the Specification that the lipid fraction, in addition to a polyunsaturated fatty acid fraction also contains a volatile oil and a sterol fraction (see p. 4, Instant specification). Therefore, *it is not the lipid fraction which contains 'primarily' C18 fatty acids, but it is the polyunsaturated fatty acid fraction which 'primarily' comprises C18 fatty acids.* Previous introduction to the claims of wherein the lipid fraction itself contained 'primarily' C18 fatty acids was considered New matter because the claims increased the amount of C18 fatty acids in the lipid fraction which were actually originally disclosed.

Applicant argues that: "To establish a *prima facie* case of obviousness, three basic criteria must be met. First there must be some suggestion or motivation, either in the references.....reasonable expectation of success....the prior art reference must teach or suggest all the claim limitations (*In re Vaeck*) (p. 8, Remarks). Applicant further cites *Ex parte Clapp* "To support the conclusion that the claimed invention is directed...either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning...." and *In re Mills*

"...may be capable...there must be a suggestion in the reference to do so" and *Ex parte Levengood* ' well within the ordinary skill of the art at the time the claimed invention was made' is not sufficient to establish a *prima facie* case of obviousness without some objective reason to modify or combine the teachings...." (pp. 8-9, Remarks).

The Supreme court has acknowledged that:

> When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. **If a person of ordinary skill can implement a predictable varition..103 likely bars its patentability**...if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond that person's skill. A court must ask whether the improvement is more than the predictable use of prior-art elements according to their established functions...
>
> ...**the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results** (see *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 U.S. 2007) emphasis added.

In addition, KSR *forecloses the argument that a specific teaching, suggestion, or motivation is required to support a finding of obviousness.* See the recent Board decision *Ex parte Smith*, --USPQ2d--, slip op. at 20 (Bd. Pat. App.& Interf. June 25, 2007) (citing KSR, 82 USPQ2d at 1396) (available at http://www.uspto.gov/web/offices/dcom/bpai/prec/fd071925.pdf).

Applicant argues that:

> Kandil (2002) provides no suggestion of formulating the disclosed lipid fraction with a pharmaceutical carrier...Kandil..fails to disclose any pharmaceutical use...rather the only utility afforded to the disclosed oily lipid fraction is an intermediate...Accordingly, there is no teaching or suggestion in Kandil..to isolate the lipid intermediate and formulate it for topical administration as 'an ointment, cream, gel, powder, balm, lotion, liquid, spray, or aerosol or as the active ingredient in a transdermal patch (p. 9, Remarks)

However, this reasoning is not convincing to overcome the outstanding rejection. It is clear that Kandil disclosed the lipid fraction as Instantly claimed by Applicant, (absent any pharmaceutical carrier) because it is explicitly seen in the same figures as disclosed by Applicant in the Instant application (the 'Lipid fraction' containing fatty acid glyceryl esters, volatile oils and total oils of Figure 1). It is true that the primary focus of Kandil was on the sterol fraction obtained via saponification of the oils to yield a fraction containing the sterols and the volatile oils. This fraction was found useful both *in-vitro* as well as *in-vivo* as an antibacterial and antifungal agent. It is *a priori* clear from Figure 1 of Kandil (2002) that the Lipid fraction also contained all of the volatile oils and sterols present in the unsaponified fraction. Therefore, the ordinary artisan would have had a reasonable expectation that the 'Lipid fraction' of Kandil would have also had antifungal and antibacterial effects because the 'Lipid fraction' inherently contained sterols shown to be medicinally effective. Further, Ramadan and Mörsel (Nahrung/Food) (2002) already taught that the oil of *Nigella sativa* L. was known in the art for treatment of fungal and bacterial infections (p. 241).

Thus, it is deemed that the ordinary artisan, having the above-cited references before him/her could have predictably ascertained that the lipid fraction of *Nigella sativa* L. seeds as disclosed by Kandil (2002) could have been used as an antifungal/antibacterial agent especially in view of Ramadan and Mörsel. It is deemed that a person of ordinary skill would have had good reason to pursue the known options within his or her technical grasp especially when choosing from a finite number of predictable solutions. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense (see *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 U.S. 2007). Since the lipid fraction of Kandil (2002) yielded a fraction which had antibacterial and antifungal activity, the ordinary artisan would have had a reasonable expectation that the lipid fraction would also have this activity, especially considering that the oil itself was already known to have these activities.

Applicant argues that the lipid fraction of Kandil is different than the lipid fraction as Instantly claimed because:

> ...Kandil (2002) clearly discloses alternative, single solvent extractions. conversely, the instant application discloses successive, multi-solvent extractions....as noted herein and previously, the lipid fraction of the instant composition clearly results from a series of extractions, first with either PE or hexane, and subsequently with 'ether, chloroform, ethylacetate, acetone, ethanol, methanol **and** water'...Reference to the 'intermediate product' in the subsequent paragraph as 'the petroleum ether extract' is merely illustrative shorthand...and does not directly negate Applicant's express statement that the lipid fraction of the instant invention arises from multi-solvent extractions rather than

> a single solvent extraction....Applicant respectfully submits that the lipid fraction of the instant invention will necessarily differ from the lipid fraction obtained by the Kandil (2002) process (p. 10, Remarks, emphasis in the original Remarks).

These arguments are not convincing, and are contradictory to what is actually taught in the Specification. The specification does teach that the seeds were exhaustively extracted with solvents of increasing polarity, however, that the *petroleum ether extract* was used *separately* to extract the *N.sativa* seeds and this was the extract which was further elucidated and tested. None of the other extracts were tested. Further, it is *a priori* clear, based upon 1) comparison of the Figures present in the Instant specification and Kandil (2002) as well as 2) the description of the extraction protocols and description of the endogenous phytochemicals present in each of the fractions that the 'lipid fraction' described by the Instant specification as well as Kandil (2002) *are in fact the same fraction comprising the same endogenous constituents.*

Applicant argues that "...the distinct extraction process of the instant invention yields an extract with unique properties, namely an *N.sativa* L. oil having a high content of polyunsaturated fatty acids....given that the *N.sativa* L. lipid fraction of the instant invention is unexpectedly and fundamentally different from the intermediate lipid fraction described in...Kandil....Kandil...cannot be considered to be an enabling disclosure of the lipid fraction now claimed...nor can it serve to anticipate or render obvious the invention of the pending claims....one skilled in the art would not expect a 'petroleum

ether or hexane extract' (as described in Kandil (2002) to be identical to a composition extracted with 8 separate solvents, in order of increasing polarity" (pp. 10-11, Remarks).

Again, it is the opinion of the Examiner that Applicant is misinterpreting what is actually disclosed in the Specification. It is clear from the Specification that the lipid fraction is obtained from the petroleum ether extract. This fact is further clarified by Figure 1 which specifically shows that it is the petroleum ether extract or the hexane extract which will produce the total lipid fraction which can be further fractioned into smaller, individual components. Again, it is noted that there is no other extract of *N. sativa* seeds, such as the methanol extract which has been tested within the Instant specification. Thus, it remains the opinion of the Office that the lipid fraction of the Instant claims and the lipid fraction of Kandil (2002) are indeed the same lipid fraction especially considering that the lipid fractions contained the same components.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patricia Leith
Primary Examiner
Art Unit 1655

September 28, 2007